K002400

AUG 3 0 2000

Section 3
ACL Advance: 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421

Contact Person:

Carol Marble, Regulatory Affairs Manager
Phone: 781-861-4467 / Fax: 781-861-4464

Summary Prepared:

August 3, 2000

Name of the Device:

ACL Advance

Classification Name(s):

81GKP	Instrument, Coagulation, Automated	
864.5400	Coagulation Instrument	Class II
81JBQ	Antithrombin III Quantitation	
864.7060	Antithrombin III Assay	Class II
81GGP	Test, Qualitative and Quantitative Factor Deficiency	
864.7290	Factor Deficiency Tests	Class II
81DAP	Fibrinogen and Fibrin Split Products, Antigen, Antiserum, Control	
864.7320	Fibrinogen/Fibrin Degradation Products Assay	Class II
81GIS	Test, Fibrinogen	
81GIL	Plasma, Fibrinogen Control	
864.7340	Fibrinogen Determination System	Class II
81KFF	Assay, Heparin	
864.7525	Heparin Assay	Class II
81GJS	Test, Time, Prothrombin	
864.7750	Prothrombin Time Test	Class II
81GJA	Test, Thrombin Time	
864.7875	Thrombin Time Test	Class II
81GFO	Activated Partial Thromboplastin	
864.7925	Partial Thromboplastin Time Tests	Class II
81GIR	Reagent, Russell Viper Venom	
864.8950	Russell Viper Venom Reagent	Class I

Identification of Predicate Device(s):

ACL Futura K951891

Description of the Device/Intended Use(s):

The ACL Advance is a fully automated, random access analyzer designed specifically for *in vitro* diagnostic clinical use in the hemostasis laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis. The system provides results for both direct hemostasis measurements and calculated parameters.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

The ACL Advance is substantially equivalent in performance, intended use and safety and effectiveness to the ACL Futura (predicate device).

Summary of in-house performance data:

Within Run Precision

Within run precision assessed over multiple runs using multiple levels of control plasma gave the following results:

Reagent	Control Level	n	Mean	%CV
Antithrombin (%)	Normal	25	109.81	2.20
	Abnormal 1	25	51.24	4.38
APC Resistance V (Normalized Ratio)	Level 1	25	2.59	5.02
	Level 2	25	1.71	3.68
APTT-SP (Seconds)	Normal	25	25.92	1.26
	Abnormal 1	25	43.91	0.98
D-Dimer (ng/mL)	Level 1	25	271.50	7.87
	Level 2	25	656.16	3.68
Factor VII (%) with PT-Fibrinogen	Normal	25	92.5	3.61
	Abnormal 2	25	24.2	5.05
Factor VIII (%) with APTT-SP	Normal	25	89.01	2.64
	Abnormal 2	25	34.89	3.80
Fibrinogen-C (mg/dL)	Normal	25	337.1	4.31
	Low Fibrinogen	25	122.2	3.37
Heparin (U/mL)	Low Heparin	25	0.22	11.54
	High Heparin	25	0.79	4.43
LAC Screen/Confirm (Normalized Ratio)	Normal	25	1.04	1.68
	Pool 1	25	2.15	6.74
Plasmin Inhibitor (%)	Normal	25	110.34	2.77
	Abnormal 1	25	56.66	4.85
Plasminogen (%)	Normal	25	106.50	1.82
	Abnormal 2	25	27.51	1.25
ProClot (%) with APTT-SP	Normal	25	84.3	4.60
	Abnormal 1	25	16.6	9.10
Protein C (%)	Normal	25	84.94	0.85
	Abnormal 1	25	46.23	1.31
Prothrombin (PT) (Seconds)	Normal	25	11.0	0.92
	Abnormal 1	25	17.8	0.63
PT-Based Fibrinogen (mg/dL)	Normal	25	271.7	2.13
	Low Fibrinogen	25	151.7	4.19
Thrombin Time-8 mL (Seconds)	Normal	25	17.70	2.04
	Low Fibrinogen	25	32.25	2.66

Summary of in-house performance data (Cont.):

Method Comparison

In method comparison studies evaluating citrated plasma samples, the ACL Advance versus the ACL Futura (predicate device) were shown to be statistically similar for the tests listed below.

Reagent	n	Slope	Intercept	r	Sample Range
Antithrombin (%)	51	0.93	4.19	0.981	29.44 – 139.95
APC Resistance V (Normalized Ratio)	55	1.06	-0.12	0.979	1.61 – 3.07
APTT-SP (Seconds)	54	0.98	-0.67	0.999	23.7 – 208.6
D-Dimer (ng/mL)	55	1.04	-12.12	0.992	243.3 – 1002.9
Factor VII (%) with PT-Fibrinogen	55	1.04	-1.21	0.994	13.5 – 149.9
Factor VIII (%) with APTT-SP	52	0.95	1.12	0.999	14.63 – 140.0
Fibrinogen-C (mg/dL)	49	1.04	-0.14	0.995	110.7 – 579.3
Heparin (U/mL)	55	0.96	0.01	0.993	0.00 – 0.91
LAC Screen/Confirm (Normalized Ratio)	55	0.967	0.01	0.997	0.86 – 2.97
Plasmin Inhibitor (%)	51	0.944	5.17	0.979	32.58 – 119.8
Plasminogen (%)	55	1.03	-1.30	0.998	14.66 – 140.10
ProClot (%) with APTT-SP	49	1.02	3.18	0.971	16.9 – 144.6
Protein C (%)	47	1.02	-1.21	0.998	24.16 – 113.10
Prothrombin (PT) (Seconds)	55	0.98	0.31	0.996	10.35 – 18.95
PT-Based Fibrinogen (mg/dL)	55	0.93	19.04	0.997	127.4 – 707.0
Thrombin Time–8 mL (Seconds)	55	0.95	1.05	0.985	15.56 – 32.8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 3 0 2000

Ms. Carol Marble
Manager, Regulatory Affairs
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02173

Re: K002400
Trade Name: ACL Advance
Regulatory Class: II
Product Code: JPA
Dated: August 3, 2000
Received: August 4, 2000

Dear Ms. Marble:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K002400

Device Name: ACL Advance

Indications for Use:

The ACL Advance is a fully automated, random access analyzer designed specifically for *in vitro* diagnostic clinical use in the hemostasis laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis. The system provides results for both direct hemostasis measurements and calculated parameters.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002400

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.019)